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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,750	09/23/2003	Victor E. Kimball	11242/320	1782
34205 7590 01/22/2009 OPPENHEIMER WOLFF & DONNELLY LLP 45 SOUTH SEVENTH STREET, SUITE 3300 MINNEAPOLIS, MN 55402				
EXAMINER				
NASSER, ROBERT L				
ART UNIT		PAPER NUMBER		
3735				
MAIL DATE		DELIVERY MODE		
01/22/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/668,750

**Applicant(s)**

KIMBALL ET AL.

**Examiner**

ROBERT L. NASSER

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**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21, 23-38 and 61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21, 23-38, and 61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI-108)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 10/28/2008 has been entered.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21, 23-38, and 61 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 1-21, 23-38, and 61 lack enablement in that it is unclear exactly what makes the surfaces in figures 4 and 5, inner and outer surfaces. It seems maybe front and back or top and bottom might be better explanations. Applicant should clarify or explain exactly what makes one of the surfaces inner and one outer.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-21, 23-29, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable Rosenberg et al 4538618 in view of Rosen et al 4228805. With respect to claim 1, Rosenberg in figure 3 has a blood flow sensor, i.e. fiber 216 which h has a head 218 exposed on its longitudinal axis and is capable of contacting 6 mucosal tissue in the upper respiratory tract. The flow sensor passes through a holder, i.e. 202 which has a passage therein through which the sensor passes, and is at least somewhat flexible (see discussion below). It is the examiner's position that the holder has a shape generally corresponding to the shape of a nostril and is capable of isolating the mucosal surface inside the nostril. In addition, the device further includes a PCO2 sensor (see column 5, line 55). It is the examiners position that there would also be an indicator for indicating the PCO2 measurement, given that the reference provides an indicator for all of the other measured values. The examiner notes that it is unclear whether the values of flow or PCO2 are displayed on indicator 36. However, Rosen shows a similar device to Rosenberg which determines the viability of tissue, which displays the measurement values, so as to alert the physician of the patient's status. As such, it would have been obvious to modify Rosenberg to use such a display, to provide more information as to the patient's condition. The examiner notes that the device of Rosenberg is capable of meeting the use where the device is held at element 202 and the sensor is positioned in contact with the digestive system of the patient. Hence, it meets the claim language. Rosenberg meets the intended function of the positioning means and meets the

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claim limitation. Claims 2-21 are rejected in that the device is capable of being positioned adjacent any of the mucosal surfaces recited. With respect to claims 23-27, in order to meet the claim language, the reference need only have a structure that is capable of performing that function. In Rosenberg, element 202 is a device that is capable of being used to hold the sensor in position adjacent a mucosal surface. As such, Rosenberg meets the intended function of the positioning means and meets the claim limitation. With respect to claims 28 and 29, the flow sensor is laser-doppler or ultrasonic (see column 5, lines 43-50). Claim 38 is rejected for the reasons given above, noting that elements 202 is at least partially flexible.

Claims 30, 37, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg et al in view of Rosen et al, as applied to claims 1-21, 23-29, and 38 above, further in view of Riccitelli et al 5166990. Riccitelli et al further teaches that it is known to monitor pH and PCO<sub>2</sub> in the same intravascular measuring device. As such, it would have been obvious to modify Rosenberg to include a pH sensor, to provide a more complete picture of the patient's condition.

Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg et al in view of Rosen et al, as applied to claims 1-21, 23-29, and 38 above, further in view of Boggett et al WO 98/20794. Boggett et al further teaches that in a microvascular monitoring device like that of Rosenberg, that it is known to monitor the rate of change of blood flow. As such, it would have been obvious to modify Rosenberg to include a rate of change of

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flow determining device, to provide amore complete picture of the patient's condition.

Claims 33-36 would be allowable if the enablement rejection were overcome. Claims 33-36 define over the art in that none of the art has the holder with a portion having a shape corresponding to the shape under the tongue, as claimed. The examiner notes that Weil 6055447 and 6126024 show the holder with a sensor for measuring perfusion, i.e. blood flow. However, the current application claims priority to both of those patents, and those patents support the current claims. As such, those patents are not usable against the current invention.

Applicant's arguments filed 10/28/2008 have been fully considered but they are moot in view of the new grounds of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT L. NASSER whose telephone number is (571)272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/  
Primary Examiner  
Art Unit 3735

RLN  
January 19, 2008